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Office of Public Health and Science and Food and Drug Administration, HHS
Dockets Management Branch (HFA-305), Docket #02N-0466
Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville, MD 20852

To Whom It May Concern:

RE: Solicitation of Public Review and Comment of Research Protocol: A Multicenter, Randomized Dose Response Study of the Safety, Clinical and Immune Response of Dryvax Administered to Children 2 to 5 Years of Age.
Docket No. 02N-0466

I am writing to this agency to express my concern over the ethics of administering a vaccine with potentially serious, if not fatal complications to forty children between the ages of 2 to 5 years. This vaccine will not be of medical benefit to the children unless they are subjected to a bioterrorist attack with smallpox. The children in the study will be put at risk for a study proposal that lacks statistical validity. The sample population is simply too small to infer the potentially negative outcome for American children.

An article, "Feds Seek Public Input on Vaccine", written by Lauren Neergaard, AP Medical Writer, refers to studies done in the 1960's in which 15 of every 1 million (approximately 1,200) people vaccinated suffered serious complications, and that one or two of those died. Data from 1968 show at least 40 people per million immunized developed potentially life-threatening complications.

When children were vaccinated for smallpox in the past, all of the people around them were also vaccinated. Today, because vaccination to smallpox is no longer routine, there is a valid concern about the possibility that the vaccinia itself might spread smallpox through an unvaccinated population. The children participating in the study will need to be taken out of day care and school for one month to ensure the physical safety of their classmates.

This social quarantine raises economic, academic and health questions. Who will supervise children so their parents can continue to work, and what plans are in place to keep the school-age children academically current? How will family members be protected? Even though the injection site will be covered with a hard to remove, extra- sticky protective shield, product failures have been known to happen. If a child touches the vaccination site, and touches his or her own eyes, he or she may become blind. If the vaccinated child touches the mucous membrane of an unvaccinated parent or sibling, smallpox could be spread among the child's family.

President Bush is proposing a voluntary immunization of 280 million people. If the results of the studies from the 1960's are applied, between 4,200 and 11,200 Americans may have potentially life-threatening complications and 280 to 560 Americans may die. This leads me to the conclusion that this is not a benign vaccine, and carries more than a minimal risk. According to the American Academy of Pediatrics, surveillance studies demonstrate that children have a higher incidence of adverse effects. I can' help but wonder how many children will have negative outcomes from a universal vaccine program.

Because of the serious complications from universal immunization with live smallpox vaccine, the American Academy of Pediatrics (AAP), in a policy statement on October 9, 2002, recommended a ring vaccination program to control an actual outbreak of smallpox. This surveillance and containment program was the approach taken to eradicate wild smallpox worldwide.

Dr. Julia McMillian of Johns Hopkins University, a spokeswoman for the AAP said, "I would certainly want these trials to be conducted before I would want my child to be vaccinated." Using a cost-benefit analysis, one could argue the benefits to society against the cost to the children involved in the study. However, the issue becomes very personal if the child in the study is your own.

Sincerely,

Elaine Edwards.

Elaine Edwards, MA, BA, RN